Remarks

By this Amendment, claim 34 has been cancelled without prejudice or disclaimer and claims 20 & 40 to 44 have amended. Applications submit that no new prohibited new matter has been introduced by the amendments. Written support for the claim amendments can be found on page 15, lines 17 to 18, original claims 1, 3, 6, and 11, and throughout the specification as originally filed. As amended, claims 20-31, 35-36, and 40 to 44 are currently under consideration.

Applicants appreciate the efforts of the Examiner in holding an interview on April 25, 2005 to discuss the merits of the prosecution in this application. The Advisory Action dated July 12, 2005 and the Final Office Action dated November 3, 2004 have been carefully reviewed and the following comments are made in response thereto. At this time however it is unclear to Applicants as to why the proposed amendment to claim 20 was not entered in the after-final amendment dated May 3, 2005. The amendment merely incorporated a feature of a dependent claim which was already under examination. As such, Applicants submit that the refusal to enter the amendment in the advisory action was improper, as the proposed amendment did not raise new issues under 35 U.S.C. 102 and 112.

Summary of the Advisory Action (July 12, 2005) and Final Office Action (November 3, 2004)

1. Claims 32, 33 and 37 to 39 have been withdrawn from consideration as being directed to a non-elected invention.

2. Claims 20 to 31, 34 to 36 and 40 to 44 were rejected under 35 U.S.C. 102(e) purportedly for being anticipated by Williams (U.S. Patent 5,731,284).

Rejection under 35 U.S.C. 102(e)

Claims 20 to 31, 34 to 36 and 40 to 44 were rejected under 35 U.S.C. 102(e) purportedly for being anticipated by Williams (U.S. Patent 5,731,284). The Examiner purports that Williams *et al.* disclose axotimizing rats under anesthesia and administering GDNF, and therefore, the cited reference inherently provides for treating mammals which are in pain with GDNF which, in turn, is argued as inherently alleviating the pain.

Applicants submit that Williams *et al.* does not anticipate the present invention because Williams *et al.* do not disclose treating a mammal suffering from pain. The timing of the administration of GDNF negates the Examiner's assertion that the rats were in pain. GDNF was not administered to the rats until after the completion of the surgery when sensory neurons were no longer being cut (see column 19, line

62 through column 20, line 12). According to the Examiner, "the axotomy cut both sensory and brain neurons and was painful or the anesthesia would not have been used" (see Office Action at page 3, lines 4 through 5). However, GDNF was not administered at the time of administration of anesthesia when the Examiner alleges the rats to be in pain. Rather, GDNF was administered following the completion of the surgery and after the body weight of each animal was recorded (see Williams *et al.*, column 20, lines 3 through 12). Furthermore, strict animal research protocols would necessitate administration of an analgesic is the animal were suffering from pain following the axotomy procedure. Accordingly, Applicants assert that there has not been any suggestion by the Examiner that the rats were suffering from pain at the time GDNF was administered.

For the reasons described above, Applicants submit that the Examiner has not provided a reasonable basis in fact that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art. In establishing a *prima facie* case of inherent anticipation, an Examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessary flows from the teachings of the applied prior art (see *Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. Inter. 1990) and MPEP 2112). The Examiner has not presented evidence in the present case to support the assertion that the axotimized rats were suffering from pain at the time of GDNF administration.

The Examiner's assertion that Williams *et al.* inherently teach treating a subject with pain with GDNF is also not supported by the cited reference's general disclosure of administering neurotrophic factors for treating the degeneration of nerve cells and loss of differentiated function that results from many different types of nerve damage including physical injury, damage due to ischemia, neurotoxins, neuropathy due to chronic metabolic diseases such as diabetes, and neurodegenerative diseases such as Parkinson's, Alzheimer's disease and Amyotrophic Lateral Sclerosis. Applicants submit that nerve damage as disclosed by Williams *et al.* does not necessarily cause pain. For example, it is of common knowledge that physical injury to the brain does not cause pain. Similarly, as previously mentioned, Alzheimer's disease, which is characterized by failure of recent memory, amnesia, disturbances in emotional behavior, and difficulty in managing spatial relationships or motor skills (see Williams *et al.* at column 2, lines 32 through 39), <u>is not associated with causing pain</u>.

Applicants respectfully assert that the Examiner has not established a prima facia case of anticipation because nerve damage does not necessarily cause a mammal to suffer from pain. The fact that a certain result or characteristic <u>may</u> occur or be present in the prior art is not sufficient to establish

the inherency of that result or characteristic (see *In re Rijckaert*, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993), *In re Oelrich*, 212 USPQ 323, 326 (CCPA 1981), and MPEP 2112). To establish inherency, the extrinsic evidence "must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient" (See *In re Roberston*, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999) and MPEP 2112). As the previous examples of physical central nervous system damage and Alzheimer's disease illustrate, nerve damage does not necessarily cause pain. For this reason, Williams *et al.* disclosure of using neurotrophic factors for treatment of Alzheimer's disease does not inherently teach that mammals suffering from the nerve damage are suffering from pain because there is merely a possibility, not a certainty, that the conditions and diseases associated with nerve damage cause the afflicted mammal to suffer from pain.

Without acquiescing to the merits of the rejection and for the sole purpose of advancing prosecution, claims have been amended to require administration of GDNF to a human suffering from pain. The Examiner's assertions discussed above are based on administration of GDNF to a rat allegedly suffering from pain. Applicants respectfully submit that Williams *et al.* do not teach administration of GDNF to a human suffering from pain and therefore does not anticipate the claimed invention.

Applicants respectfully request reconsideration of the subject application in view of the above remarks and withdrawal of the rejections. It is respectfully submitted that this application is now in condition for allowance. Should the Examiner believe it to be useful, an interview with the Examiner is respectfully requested in order to discuss the foregoing claims.

If there are any fees due in connection with the filing of this amendment, please charge the fees to our Deposit Account No. 50-310. If a fee is required for an extension of time under 37 C.F.R. 1.136 not accounted for above, such an extension is requested and the fee should also be charged to our Deposit Account.

Respectfully submitted
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Dated: **December 5, 2005**
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